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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/591,800 | 07/09/2007 | Hongyue Dai | ROSA134299 | 3177 |

26389 7590 11/16/2010

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| EXAMINER | |
|---|---|
| SMITH, CAROLYN L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/16/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/591,800 | DAI ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn Smith | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29,42,54,58-67,89,90 and 94-105* is/are pending in the application.

4a) Of the above claim(s) *54,59,61-67,94,96 and 98-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,42,58,60,89,90,95,97 and 105* is/are rejected.

7)☒ Claim(s) *54, 59, 61-67, 94, 96, and 98-104* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendments and remarks, filed 9/2/10, are acknowledged. Amended claims 29, 42, 58-67, 89, 95-104 and cancelled claims 1-28, 30-41, 43-53, 55-57, 68-88, and 91-93 are acknowledged.

Applicant's arguments, filed 9/2/10, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims herein under examination are 29, 42, 54, 58-67, 89-90, and 94-105.

### *Claim Rejections – 35 USC §102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 42, 58, 60, 89, 90, 95, 97, and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al. (US 2004/0058340 A1). This rejection is maintained and reiterated for reasons of record.

Dai et al. disclose a computer-implemented method for assigning an individual having breast cancer to one of a plurality of categories in a clinical trial as well as predicting a good or bad prognosis (abstract, 0014, 0021) by classifying (ER- and BRCA1) or (ER- and sporadic) (0003, 0012-0016, 0025-0026, 0045-0046, 0074, 0085, 0093-0094, 0118, 0165) determining a profile comprising measurements of expression levels from 2 genes as well as transcript levels (i.e. AF055033, NM_000599; AF005487, Contig50728_RC, Contig53598_RC, NM_002888, NM_005218, U17077) (0013-0016, 0025, 0034, 0090-0092, 0119, Table 1), classifying an individual as having good or poor prognosis (0014, 0026) via comparing similarities to templates above or below a threshold with templates based on levels from good or bad outcome patients (i.e. non-reoccurence vs. reoccurrence of metastases) (0003, 0026-0029, 0131-0148, 0328-0329), and assigning to one category in a clinical trial if the individual has a good prognosis and to a second category if the individual has a poor prognosis (abstract, 0021; claim 40), as stated in instant claims 29, 42, 58, 60, 89, 90, 95, 97, as well as using average expression levels (0027, 0052, 0064, 0157, 0329), as stated in instant claim 105.

Thus, Dai et al. anticipate instant claims 29, 42, 58, 60, 89, 90, 95, 97, and 105.

Applicant summarizes Dai et al. and the instant invention. Applicant argues Dai et al. do not disclose a method for assigning an individual to one category in a clinical trial if said individual is classified as having a good prognosis, and assigning said individual to a second

category in said clinical trial if said individual is classified as having a poor prognosis, wherein said good or poor prognosis is determined by different sets of marker genes depending on whether the patient is ER- and sporadic; ER- and BRCA1; ER+ and ER/AGE high; ER+, ER/AGE low and LN+; or ER+, ER/AGE low and LN-. This statement is found unpersuasive as Dai et al. classifies ER- and sporadic as well as ER- and BRAC1 (i.e. 0016, 0025-0026, 0045-0046, 0074, 0085, 0093-0094, 0118, 0165). It is noted that only one of the classifying groups must be present in the prior art to anticipate instant claim 29. Dai et al. disclose assigning an individual to one category in a clinical trial if said individual is classified as having a good prognosis, and assigning said individual to a second category in said clinical trial if said individual is classified as having a poor prognosis (0021). Applicant argues Dai et al. do not use a comprehensive prognosis based on classifying an individual as ER- and sporadic; ER- and BRCA1; ER+ and ER/AGE high; ER+, ER/AGE low and LN+; or ER+, ER/AGE low and LN- followed by determining good or poor prognosis. This statement is found unpersuasive for reasons discussed above. Applicant argues the specification states on page 98 that the comprehensive prognosis of the instant invention improves the prediction error rate when compared with the 70 gene classifier. This statement is found unpersuasive as Dai et al. disclose combining all clinical parameters in a group (0285-0291) and multivariate analysis (0339-0340). Applicant's arguments are deemed unpersuasive for the reasons given above.

***Conclusion***

Claims 54, 59, 61-67, 94, 96, and 98-104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

November 8, 2010

/Carolyn Smith/
Primary Examiner
AU 1631